

Keeping it lean: hitting the Goldilocks level of detail in medical writing

It is crucial to apply lean medical writing principles when drafting regulatory documents, to ensure they are as informative as possible while being concise and readable – how can this be achieved?

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The principles of lean medical writing continue to gain attention for their potential to enhance efficiency and encourage brevity while maintaining clarity and reliability. Yet, despite a growing awareness of the concept of lean writing, it is still not being widely applied. Instead of preparing documents that focus on key data and use concise language to communicate the sponsor's interpretation of what those mean, companies continue to generate long-winded data dumps.

In 2021, the American Medical Writers Association (AMWA) ran a survey of health authority assessors from around the globe to get their view on the documents they review. In the opinion of these agency assessors, the number one quality problem identified in the documents is 'excessive length, repetition, verbosity'.¹ As Gregory Cuppan put it, agency reviewers are overwhelmed by the 'infobesity' of the documents we put in front of them.² The difference between simply presenting data and using it to make a compelling argument for the regulatory authorities (ie, storage vs story) is often not understood or practised.³



Understanding the right amount of information requires thinking about the reader and what they need from the text. Each section of a document should focus on the purpose that section is designed to communicate. Why are we talking about demographic data? What are we trying to understand when looking at adverse events of special interest? Instead of just regurgitating bulky text that lists the data, what we write should provide answers to those questions.

It is incorrect to think that our job in writing regulatory documents is to just state the facts (ie, the data) and let the assessor decide what they mean. Our job is to communicate to the assessor what we believe the data mean.

A clinical team has a much deeper understanding of all the nuances in the data than the assessors can ever have. From understanding everything that happened in each of the specific studies that may have impacted the outcomes to a rich clinical perspective on the therapeutic area, we are bringing our full understanding of the context into play, which is an important part of providing the assessor with a complete understanding of the whole picture. This means the text we write should focus on what we believe the data mean in this big picture.

Good lean writing begins with eliminating textual lists of data and focusing on the message, which does

not mean there is no data at all in the text. A common misunderstanding of lean writing is that it just points at the data source. Saying 'The demographic data are in Table 2.' is not lean – it is simply a cross-reference. If all we were going to do is point the assessors to the data, we would not need to write any text at all; we could just send them the tables, figures and listings with a table of contents.

So lean writing does not just mean as little as possible. The goal of lean writing is to put in just the right amount of data to give sufficient context without overloading the text. To understand how much is needed, put yourself in the shoes of a reader. If the text says:

Demographic characteristics were similar in all treatment groups (Table 2). In all groups there were more men than women and most participants were adults and not overweight.

Is the reader able to decide on their own if this is true? No. They need to go to the table and find the data that support these statements. What proportion of men vs women has been used to decide there is more? Is it 51% or is it 88%? A text without any data at all makes the reader work before they can decide if they agree with the statement. If the text were to read:

Demographic characteristics were similar in all treatment groups (Table 2). Across all groups there were more men (80%) than women and most participants were White (84%) adults (mean age: 36 years) and not overweight (mean BMI: 25 kg/m²).

This gives the reader the key data points to support the interpretation. The reader can decide on the spot if they agree with the message or not. If they want further details, they can then go to the table to see supporting data (SDs, ranges, confidence intervals, etc), but they have the essential information built in to aid





assessment of this statement. This is the Goldilocks amount of information to present in the text: just enough to put the statements into context, but not so much that readability is lost and it becomes bulk.

Lean writing is also about reducing unnecessary language and repetition. Instead of saying the same thing in multiple places, we can reduce the bulk and the risk of inconsistencies between sections saying the same thing by selecting one relevant place to present a particular idea and then using cross-references to refer to it from anywhere else (particularly between documents in a submission dossier). This will eliminate duplication.

We also need to remember that these are scientific documents and not elegant works of literature. The goal here is not to demonstrate how creatively we can describe the data; it is to help the assessor find things and quickly understand the points we are making. They should be fit for purpose. By eliminating unnecessary words and even entire clauses, a reader gets to the point faster. This does not mean we write texts that do not flow. Nobody wants to read 'Jane came in. Priya ate some toast. Axel went to bed.' Conjunctions and connecting thoughts are still important. It just means removing text that adds no additional meaning to the sentence. As a common example, introductory clauses are frequently

tagged onto sentences without adding any real additional meaning. Compare these 2 sentences:

When comparing dogs to cats, dogs are almost always heavier than cats.

Dogs are almost always heavier than cats.

If we remove the introductory clause from the first one, is anyone unclear about the fact that we are comparing dogs and cats in the second sentence? No. The second sentence has all of the meaning of the first sentence without the added bulk. Similarly, words that simply repeat an idea that is already obvious can be eliminated.⁴ For example, 'during the summer months' vs 'during the summer' or 'a 3-year-old child' vs 'a 3-year-old'. This is a key part of lean writing. Use the minimum number of words to express the full thought. It will generally be more concise and certainly much faster to read.

The goal of medical writing is to aid review and assessment by agencies so we can get medications and therapies to patients faster. We are not writing these documents for someone to snuggle up with next to a fire and savour on a cold winter's night. They are about precision and speed of delivery. The faster an assessor can find the information they are looking for and get a clear understanding of the sponsor's interpretation of the data set, the faster they can build their own

opinion about the product. Moreover, lean documents take less time to write (if medical writers have been trained appropriately), to review by internal teams and for quality control. There is increased speed of production in addition to faster and more effective processing time by the end user.

So why is there so much resistance to lean writing, particularly among academics who enter the workforce of pharmaceuticals? Partially, it is because humans are creatures of habit, and we are very good at perpetuating the bad habits of our predecessors. We were all weaned on long-winded academic publications with poor focus and lack of clear messages. For decades, the idea that 'data speak for themselves' was the tenet, and we were meant to just let the data stand in its pureness so that everyone could intuit what it meant. The reality is that we, with our brains and our analytical skills, interpret the data and put it into the context of everything else we know. This is why three different people may interpret the same data point (in all its purity) differently. We all have different knowledge bases, and we look at things from different angles. That is precisely the value and importance of having a team look at the data, so that we can discuss and align on what it all means. The totality of the meaning we elucidate as a team is what we are charged with communicating to the agency assessors, so they can look at the data and see if they agree with us.

It is our responsibility to tell them what we think it means because this is the basis of scientific debate and deduction.

Another reason lean writing has been slow in adoption is because it takes time and effort to instil change. Organisations and individuals accustomed to traditional writing practices may resist using new, leaner approaches. They often do not understand exactly what is needed and feel it's safer to do it the way it was done last time: "The last dossier got the approval, right? So don't fix what isn't broken."

To ensure lean writing is applied effectively, medical writers need to be taught what it really is and how to wield it. Yet, training needs to extend beyond the medical writers to everyone involved in reviewing and contributing to these documents. It is a lesson in frustration for medical writers to be crafting good lean texts only to have the management reviewing their documents insist on adding back in all the bulk. Everyone needs to learn and master lean writing principles and, more importantly, understand why this is so important. Presenting vast amounts of data succinctly and clearly is a real challenge that takes a unified approach from an entire team.

Achieving consistency in lean writing across different teams and departments will be more likely if companies develop robust standardisation of templates, style guides and processes. Companies should instil a methodology of applying lean writing that would include:

- Training teams about what it is, why it is essential and how to use it. This applies to the medical writers, quality control specialists and the authoring teams
- Building the idea into standard operating procedures (SOPs)

and/or work instructions so it is formally recognised

- Having the quality control or editorial check review specifically for good lean writing principles, and suggest improvements if they are not applied.

Successful adoption of lean authoring will depend on everyone buying into the concept, from top to bottom of an organisation. It will require advocacy from senior leadership and socialisation to gain support from authors, teams and management.⁵ Once established and incorporated into the ways of working, it will not only enhance operational efficiency, but also strengthen the overall quality and impact of medical writing outputs in the healthcare industry. By applying solid lean writing principles, we are making the lives of the agency assessors easier through better readability and understanding of the scientific and medical content that will ultimately lead to faster approvals. For, if it isn't well written, it will never be well read.

References:

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